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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,348	02/14/2002	Jotham Wadsworth	PC10030D	9919

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EXAMINER	
COLEMAN, BRENDA LIBBY	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,348	WADSWORTH ET AL.	
	Examiner	Art Unit	
	Brenda Coleman	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8,10 and 15-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,10 and 15-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6, 8, 10 and 15-35 are pending in the application.

Specification

1. The disclosure is objected to because of the following informalities: the new paragraph that was added at page 7, after line 14 indicates that the definition of the variables R^5 and R^6 are as defined in claim 2.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-6, 8, 10 and 15-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the pharmaceutical compositions of the compounds of formula I, does not reasonably provide enablement for the complex compositions of formula I as claimed herein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The pharmaceutical compositions of the instant invention where an additional active ingredient such as an **antidepressant**, a **muscarinic agonist**, a **neurotrophic factors**, an **agent that slows or arrests Alzheimer's disease**, an **amyloid aggregation inhibitior**, a **secretase** inhibitor, a **tau kinase** inhibitor, a **neuronal anitinflammatory agent** and an **estrogen-like therapeutic agent** is included in the compositions. The

specification does not define the that which is intended in the additional active ingredients, i.e. which antidepressants, muscarinic agonists, neurotrophic factors, etc.

3. Claims 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are two species, which are not described in the specification, i.e. 2-fluoro-N-(4-hydroxy)-10-aza-tricyclo[6.3.1.$0^{2,7}$]dodeca-2(7),3,5-trien-5-yl)-benzamide and 4,5-bistrifluoromethyl-10-aza-tricyclo[6.3.1.$0^{2,7}$]dodeca-2(7),3,5-triene.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 1, 8, 10 and 15-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in Ex parte Wu, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such

as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of Ex parte Steigewald, 131 USPQ 74 (Bd. App. 1961); Ex parte Hall, 83 USPQ 38 (Bd. App. 1948); and Ex parte Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 (and claims dependent thereon) recite the broad recitation "aryl and heteroaryl groups may optionally be substituted with one or more substituents", and the claims also recite "preferably from zero to two substituents" which is the narrower statement of the range/limitation.

b) Claims 15-35 recite the limitation "and pharmaceutically acceptable salts thereo" in each of the species claims. There is insufficient antecedent basis for this limitation in the claim.

c) Claim 24 is vague and indefinite in that it is not known what is meant by "a pharmaceutical composition wherein **the antidepressant** is a tricyclic antidepressant or a serotonin reuptake inhibiting antidepressant". It is not known what antidepressant this refers to in this independent claim.

d) Claim 25 is vague and indefinite in that it is not known what is meant by "a pharmaceutical composition wherein **the neurotrophic factor is NGF**". It is not known what neurotrophic factor this refers to in this independent claim.

e) Claim 25 is vague and indefinite in that it fails to end with a period, indicating the end of the claim.

f) Claim 26 is vague and indefinite in that it is not known what is meant by "a pharmaceutical composition wherein **the agent that slows or arrests Alzheimer's disease** is a cognition enhancer". It is not known what agent this refers to in this independent claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6, 8, 10, 15-19, 22, 24-27 and 30-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/348,381. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are embraced by the compositions and method of use of the

compounds of the formula where R^1 is hydrogen or ethanone, and R^2 and/or R^3 are methyl, fluoro, trifluoromethyl, nitro, chloro, cyano, hydroxyl, etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-6, 8, 10, 15-19, 22, 24-28 and 30-35 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/348,399. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are embraced by the compositions and method of use of the compounds of the formula where R^1 is hydrogen or ethanone, and R^2 and/or R^3 are methyl, fluoro, trifluoromethyl, nitro, chloro, cyano, hydroxyl, etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1, 3-6, 8, 10 and 15-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-10 of copending Application No. 10/075,843. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compositions and method of use of the compounds of formula I of the instant invention are embraced by the compositions and method of use of the compounds of formula (I) where R^1 is hydrogen, $(C_1\text{-}C_6)$alkyl, unconjugated $(C_3\text{-}C_6)$alkenyl, $XC(=O)R^{13}$, benzyl or

$-CH_2CH_2$-O-(C_1-C_4)alkyl, and R^2 and R^3 are hydrogen, (C_2-C_6)alkenyl, (C_2-C_6)alkynyl, hydroxyl, nitro, amino, halo, cyano, etc.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 3, 8, 10 and 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,605,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the open claim language of the composition claims of U.S. '610, embraces the compositions of the instant invention with the additional active ingredients.

9. Claims 1-6, 8, 10 and 24-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-14 of U.S. Patent No. 6,410,550. Although the conflicting claims are not identical, they are not patentably distinct from each other because the open claim language of the composition claims of U.S. '550, embraces the compositions of the instant invention with the additional active ingredients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brenda Coleman

Brenda Coleman
Primary Examiner Art Unit 1624
May 17, 2004